UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re FENOFIBRATE PATENT LITIGATION	:	ECF Case No. 1:11-md-02241 (JSR)

PLAINTIFF LUPIN ATLANTIS HOLDINGS S.A.'S AND PLAINTIFF/DEFENDANT ETHYPHARM S.A.'S JOINT OPENING CLAIM CONSTRUCTION BRIEF

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’574 patent	U.S. Patent No. 7,101,574
’331 patent	U.S. Patent No. 7,863,331
Lesciotto Ex. __	The corresponding exhibit to the Declaration of Kate M. Lesciotto in Support of Plaintiff Lupin Atlantis Holdings S.A.’s and Plaintiff/Defendant Ethypharm S.A.’s Joint Opening Claim Construction Brief, filed concurrently herewith
__:__	The column and line numbers, respectively, of a U.S. patent

I. INTRODUCTION

Plaintiff Lupin Atlantis Holdings S.A. ("LAH") and Plaintiff/Defendant Ethypharm S.A. ("Ethypharm") (collectively, "LAH/Ethypharm") jointly submit this claim construction brief to address the disputed terms of the '574 and '331 patents. The LAH/Ethypharm proposed constructions, set forth in Appendix A, attached, are based on the plain language of the claims, as properly informed by the respective specifications and prosecution histories of the '574 and '331 patents.

Defendants Paddock Laboratories, Inc., Cerovene, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, Ranbaxy Inc., Ranbaxy Pharmaceuticals, Inc., Apotex, Inc. and Apotex Corp. (collectively, "Defendants"), propose definitions which do not comport with the plain wording of the claims themselves, and further attempt to impermissibly import into the claims various limitations from the specification, as well as limitations not found elsewhere in the claims or prosecution history. Defendants motive, of course, is to avoid a finding of infringement.

LAH and Ethypharm respectfully request that the Court follow decades of precedent and construe the claims consistent with the intrinsic evidence. Such evidence is dispositive of the meaning of the disputed claim terms and, in the present action, fully supports the LAH/Ethypharm proposed constructions set forth in this brief.

II. BACKGROUND OF THE TECHNOLOGY

A. The '574 Patent

As the title of the patent indicates, "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method," the '574 patent concerns pharmaceutical compositions containing fenofibrate, as well as methods of preparing such pharmaceutical compositions. Lesciotto Ex. A. The claim construction issues before the Court, however, only concern language in claims that

are directed to the pharmaceutical compositions. All of the disputed terms in the '574 patent are found in independent claims 1 and 19:

> 1. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant, and wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition, and further wherein said binding cellulose derivative represents between 2 and 15% by weight, relative to the weight of said pharmaceutical composition.
>
> 19. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization agent, wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1.

Id. at 10:28-38; 11:30-35 (disputed terms are underlined).

As noted in the specification, the active pharmaceutical ingredient fenofibrate was known to treat hypercholesterolemias, hyperlipidemias, and hypertriglyceridemias. *Id.* at 1:9-11. Fenofibrate is very poorly soluble in water, resulting in limited bioavailability and limited absorption in the digestive tract. *Id.* at 1:23-26. Thus, the prior art explored various ways to improve the rate of solubilization of fenofibrate, including reducing the particle size of the fenofibrate by use of techniques such as micronization and comicronization of the fenofibrate with a surfactant. *Id.* at 1:27-30. However, the inventors of the '574 patent unexpectedly discovered that the incorporation of a low proportion of a cellulose derivative, which functions both as a binder and a solubilization adjuvant, into a pharmaceutical composition containing a high proportion of micronized fenofibrate and a surfactant, resulted in a composition having greater bioavailability than prior art formulations, including those using micronized fenofibrate. *Id.* at 2:4-10. The resulting fenofibrate composition, comprising a high proportion of micronized

fenofibrate, allows for a smaller dosage size than prior art formulations, advantageously providing for easier administration. *Id.* at 2:27-31.

The claimed pharmaceutical composition is in the form of granules, each granule "compris[ing] a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant." *Id.* at 10:29-32. The binding cellulose derivative is present at a much lower concentration than previous fenofibrate formulations, representing "between 2 to 15% by weight, relative to the weight of [the] pharmaceutical composition" or being present in an amount "wherein the mass ratio of [the] fenofibrate to [the] binding cellulose derivative is between 5/1 and 15/1." *Id.* at 10:36-38; 11:34-35. As discussed, this low proportion of functional cellulose derivative combined with the high proportion of fenofibrate unexpectedly provides increased bioavailability and an easily administrable dosage form. *Id.* at 2:27-31; Examples 1C and 2B.

B. The '331 Patent

The '331 patent, a continuation-in-part of the '574 patent, claims a method of reducing food effect when treating hypertriglyceridemias and/or hypercholesterolemias and/or hyperlipidemias by administration of a pharmaceutical composition containing micronized fenofibrate as the active ingredient. Lesciotto Ex. B at 16:48-18:4. All of the disputed terms are found in claim 1, the sole independent claim of the '331 patent:

> 1. A method of reducing food effect when treating hypertriglyceridemias and/or hypercholesterolemias and/or hypertriglyceridemias in a patient in need thereof comprising administering to said patient a therapeutically effective amount of a pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising:
>
> (a) a neutral core; and
>
> (b) an active layer, surrounding the neutral core;
>
> wherein said neutral core comprises a sugar or a sugar mixed with

> starch; said active layer comprises the micronized fenofibrate, the surfactant, and the binding cellulose derivative; and wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1, and said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition.

Id. at 16:48-67 (disputed terms are underlined).

As in the '574 patent, the '331 patent notes the problem of fenofibrate's poor solubility and the various prior art approaches to solving this problem. *Id.* at 1:10-2:24. The specification of the '331 patent further notes that, due to its poor solubility in water, fenofibrate is much better absorbed after the ingestion of a high fat meal rather than fasting conditions. *Id.* at 1:29-42. This is referred to as a "food effect." *Id.* However, patients who are being treated with fenofibrate are usually on controlled diets which restrict the patients' fat intake. *Id.* Thus, a method of reducing this food effect, and obviating the need for a high fat meal when taking fenofibrate, would be greatly beneficial. The claims of the '331 patent are directed to a subset of the pharmaceutical compositions disclosed in the '574 patent, that are utilized to reduce the known food effect with respect to fenofibrate. *Id.* at 2:58-67. In other words, the pharmaceutical compositions claimed in the '331 patent are less dependent on the presence of food to achieve high levels of bioavailability, as compared to prior art fenofibrate formulations. *Id.*

The pharmaceutical compositions described in the claims of the '331 patent differ in scope from those of the '574 patent in several respects. For example, whereas the claims of the '574 patent use the broader language of "binding cellulose derivative as a solubilization adjuvant," the claims of the '331 patent are specific to "hydroxypropylmethylcellulose," which is a particular type of binding cellulose derivative. *See, e.g., id.* at 4:6-9. Additionally, the '331 patent claims a "neutral core" which "comprises a sugar or a sugar mixed with starch," while the compositions of the '574 patent require a "neutral microgranule" without any limitations on

particular substrates. *Compare, e.g.*, Lesciotto Ex. A at 10:29 *and* Lesciotto Exhibit B at 16:60-61. The claims of the '331 patent are directed to the use of such a specific pharmaceutical composition. Lesciotto Ex. B at 16:48-64.

III. ARGUMENT

A. Legal Standards for Claim Construction

It is a bedrock principle that the claims of a patent define the scope of the invention. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). In construing the claims, a court should begin first with the intrinsic evidence—*i.e.*, the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). However, "[a]ll intrinsic evidence is not equal." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). As such, "a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (quoting 35 U.S.C. § 112, ¶ 2) (omissions in original). While the specification may provide a context for the claims, the Federal Circuit has recognized that "a court may not read a limitation into a claim from the specification." *Id.* at 1116-17. This is in line with a long standing warning by the Supreme Court against using the specification to alter the plain meaning of the claims:

> Some persons seem to suppose that a claim in a patent is like a nose of wax, which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is. The claim is a statutory requirement, prescribed for the very purpose of making the patentee define

> precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.

White v. Dunbar, 119 U.S. 47, 51-52 (1886).

Further, when construing various claim terms, a court should be conscious of defining the terms in such a way which preserves claim differentiation. "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005).

Additionally, the prosecution history may be of critical significance when construing claims. *Vitronics Corp.*, 90 F.3d at 1582. For example, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention." *Phillips*, 415 F.3d at 1317.

While other sources may be considered by a court when conducting claim construction, such sources, including extrinsic evidence, may not be used "to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324. Ultimately, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

Finally, while the '574 and '331 patents are related, statements made during the respective prosecution history of one patent cannot automatically be attributed to the other, particularly in view of the different specifications and the different claim terms. *See Saunders Group, Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007) ("When purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply.");

Ventana Med. Sys. v. Biogenex Labs. Inc., 473 F.3d 1173, 1182 (Fed. Cir. 2006) (noting that "the doctrine of prosecution history disclaimer generally does not apply when the claim term in the descendent patent uses different language"). Significantly, various district courts have expressed wariness over the "upstream" use of prosecution history disclaimer—*i.e.*, using statements made during the prosecution of a child patent to inform the claim construction of the parent patent. *See Winn Inc. v. Eaton Corp.*, 272 F. Supp. 2d 968, 977 n.5 (C.D. Cal. 2003) (noting the lack of authority for and rejecting the use of "a subsequent patent to determine the meaning of claim terms used in a prior patent"); *Epic Metals Corp. v. Consol. Sys., Inc.*, 19 F. Supp. 2d 1296, 1303 (M.D. Fla. 1998) (concluding that a continuation-in-part patent's specification and prosecution history were extrinsic evidence with respect to construing claims of the parent patent and rejecting such extrinsic evidence as a "disserv[ice to] the public's right to rely on the [parent] patent's language"); *see also Scientific Games Int'l, Inc. v. Oberthur Gaming Techs.*, No. 1:02-cv-3224-TWT, 2005 WL 3307522, at *6 (N.D. Ga. Dec. 5, 2005) (finding that a related patent application amounted to extrinsic evidence and declining to consider this extrinsic evidence with respect to the construction of the patents-in-suit unless a genuine ambiguity remained after consideration of the intrinsic evidence) (citing *Epic Metals Corp.*, 19 F. Supp. 2d at 1303).

B. Terms Relating to "Pharmaceutical Composition"

1. "A pharmaceutical composition" and "said pharmaceutical composition" in the '574 Patent

Disputed Term	LAH/Ethypharm Construction	Defendants' Construction
"a pharmaceutical composition"	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: "A composition which is suitable for pharmaceutical use"	all of the active and inactive ingredients in the final dosage form

"said pharmaceutical composition"	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: "The pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent"* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form

The disputed claim term "a pharmaceutical composition" appears in the preamble of both claims 1 and 19 of the '574 patent. The LAH/Ethypharm proposal for this term is based on the claim language itself, which needs no further construction. A person of ordinary skill in the art would immediately understand what the general term "a pharmaceutical composition" is intended to convey, as it is a broad term applicable to various types of compositions which are suitable for pharmaceutical use.

The claims go on to clearly define what "said pharmaceutical composition" is in the context of the '574 patent: granules, wherein each granule comprises a neutral microgranule on which is a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent. Lesciotto Ex. A at 10:28-38, 11:30-35. Thus, "said pharmaceutical composition" provides a composition useful for a purpose, and is not limited to a final dosage form. In the case of the '574 patent, this pharmaceutical composition consists of granules, each of which comprises a neutral microgranule on which is a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization

adjuvant/agent. *See Phillips*, 415 F.3d at 1312 ("Because the patentee is required to 'define precisely what his invention is,' the [Supreme] Court explained, it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'") (quoting *White*, 119 U.S. at 52); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999) (noting that "a court must presume that the terms in the claim mean what they say").

The LAH/Ethypharm proposal—to follow the plain language of the claims—comports with how the prior art pharmaceutical compositions were characterized by the patentees during the prosecution of the '574 patent—namely, as granules, each of which comprises a neutral microgranule on which is a composition. The patentees stated that "[t]he composition of the suspension [of the prior art formulation] is quite different than the final composition of *the pharmaceutical formulation (i.e., the coated granules)*." Lesciotto Ex. C at p. 14 (emphasis added). Thus, even when comparing the claimed composition to prior art compositions, the patentees were consistent in equating the "pharmaceutical composition" defined by the claims of the '574 patent with only the granules, each of which comprises a neutral microgranule on which is a composition—and not any final dosage form (that may contain additional ingredients).

Perhaps more significantly, in describing the second declaration of George Bobotas, Ph.D. which was submitted to the U.S. Patent and Trademark Office ("PTO") during the prosecution of the '574 patent, the patentees noted that Dr. Bobotas calculated the weight percentages of micronized fenofibrate and binding cellulose derivative in Antara®, a commercial embodiment of the '574 patent, based *only* on the weight of the granules, each of which comprises a neutral microgranule on which is a composition. Specifically, the claims of the '574 patent recite "greater than or equal to 60% by weight" fenofibrate and "between 2 and 15% by

weight" binding cellulose derivative, relative to the weight of "said pharmaceutical composition." Lesciotto Ex. A at 10:28-38; 11:30-35. Dr. Bobotas calculated the weight percentages of micronized fenofibrate and binding cellulose derivative in Antara® as follows: "The 130 mg ANTARA® formulation of the invention is 64% fenofibrate by weight *relative to the weight of the granules*, and 12% by weight binding cellulose derivative, *relative to the weight of the granules*. Thus, the 130 mg ANTARA® formulation is within the instant claims." Lesciotto Ex. D at p. 10 (internal citation omitted) (emphasis added). *See also* Lesciotto Ex. E at p. 2, ¶ 4. Accordingly, the term "said pharmaceutical composition" as used in the claims of the '574 patent, refers only to the coated granules.

In contrast, Defendants' proposed constructions improperly equate each of the "pharmaceutical composition" terms in claims 1 and 19 of the '574 patent to a final dosage form, rather than to only the portion of a final dosage form that contains the active components and is intended to achieve a therapeutic effect (*e.g.*, the granules, which are specifically defined in the '574 patent as each comprising a neutral microgranule on which is a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent). Such a construction goes far beyond the plain language of the claim. *See Johnson Worldwide Assocs., Inc.*, 175 F.3d at 989 ("a court must presume that the terms in the claim mean what they say").

A simple illustration puts the logical error of Defendants' proposals in clear view. The claims of the '574 patent clearly convey the meaning of "said pharmaceutical composition"—namely, that "said pharmaceutical composition" is in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent. If these

granules were then mixed with inert silica beads and the mixture placed into a capsule, under Defendants' construction, the silica beads would comprise a portion of the pharmaceutical composition. Although such beads are not part of the claimed pharmaceutical composition, Defendants' proposal would effectively encompass the non-functional beads. Based on the intrinsic evidence, the claimed pharmaceutical composition is only the collection of coated granules, as defined by the claims. Anything else present in a capsule or other dosage form is not part of the claimed pharmaceutical composition.

2. "A pharmaceutical composition" and "the composition" in the '331 Patent

Disputed Term	LAH/Ethypharm Construction	Defendants' Construction
"a pharmaceutical composition"	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
"the composition"	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising: (a) a neutral core; and (b) an active layer* *the underlined disputed terms are understood to incorporate the LAH/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form

Similar to the "pharmaceutical composition" terms found in the '574 patent, LAH and Ethypharm believe that no further construction is necessary for the terms "a pharmaceutical composition" or "the composition" in the '331 patent. *See* Section III.B.1., *supra*. The general term "a pharmaceutical composition" would be understood exactly as it is written—a composition suitable for pharmaceutical use. There is no need for the Court to expend time construing such a commonly understood term, as Defendants request. However, if such a construction is deemed to be warranted, LAH and Ethypharm assert that their proposed construction of "a composition suitable for pharmaceutical use" should be adopted over the construction advanced by Defendants.

Claim 1 of the '331 patent clearly defines "the composition"—namely, a composition comprising micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising: (1) a neutral core; and (b) an active layer. Lesciotto Ex. B. at 16:48-67. As with the '574 patent, "the composition" of the '331 patent is not intended to cover a final dosage form, but rather to be a composition useful for such purpose, wherein the composition consists of granules that comprise (1) a neutral core, and (2) an active layer. *See Phillips*, 415 F.3d at 1312 ("Because the patentee is required to 'define precisely what his invention is,' the [Supreme] Court explained, it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'") (quoting *White*, 119 U.S. at 52); *Johnson Worldwide Assocs., Inc.*, 175 F.3d at 989 (noting that "a court must presume that the terms in the claim mean what they say").

Further, such a construction is in accord with the prosecution history. As noted in the Appeal Brief filed during the prosecution of the '331 patent, "[t]he claimed formulation is a neutral core, and an active layer surrounding the neutral core." Lesciotto Ex. F at p. 1.

Additionally, in a declaration submitted to the PTO, Dr. George Bobotas performed a comparison between a pharmaceutical formulation covered by the claims of the '331 patent, *e.g.*, Antara®, with prior art formulations.[1] Lesciotto Ex. G. As discussed in Section III.B.1., *supra*, Bobotas II calculated the weight percentage of binding cellulose derivative, specifically hydroxypropylmethylcellulose in the case of Antara® and the '331 patent, relative to the weight of the granules. *See* Lesciotto Ex. D at p. 10 (internal citation omitted) (emphasis added) ("The 130 mg ANTARA® formulation of the invention is . . . 12% by weight binding cellulose derivative, *relative to the weight of the granules*. Thus, the 130 mg ANTARA® formulation is within the instant claims."); *see also* Lesciotto Ex. G at p. 2, ¶ 4. It is telling that the weight of the capsule that is part of the ANTARA® finished dosage form was not included in that weight analysis. The '331 prosecution history thus corroborates the LAH/Ethypharm proposed construction of the term "the composition."

Defendants' proposed constructions for the "pharmaceutical composition" terms in the '331 patent are contrary to the intrinsic evidence, as are their constructions for the '574 patent.

[1] There were two declarations submitted by Dr. Bobotas. The first declaration ("Bobotas I") compared the bioavailability of an inventive formulation covered by both the '574 and '331 patent, namely Antara®, with prior art fenofibrate formulations. *See* Lesciotto Exs. G and H. Bobotas I was submitted during the prosecution of both the '574 and '331 patents. The second declaration ("Bobotas II") confirmed that Antara® had 64% by weight fenofibrate and 12% by weight binding cellulose derivative. *See* Lesciotto Ex. E. In the case of Antara®, the binding cellulose derivative is hydroxypropylmethylcellulose. *See* Lesciotto Ex. G at ¶ 4 (stating that Antara® is covered by the '331 patent). Bobotas II was submitted during the prosecution of the '574 patent, but is equally applicable to the '331 patent as it provides information relating to Antara®, which is covered by the pharmaceutical compositions described in the claims of both patents.

C. Terms Relating to "Granule"

1. "Granules", "Granule," and "Each granule" in the '574 Patent

Disputed Term	LAH's/Ethypharm's Construction	Defendants' Construction
"granules"	Neutral microgranules on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent.	many discrete granules
"granule"	Neutral microgranule on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent.	neutral microgranule on which is sprayed a suspension of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent
"each granule"	No additional construction necessary	each and every granule in the pharmaceutical composition contains all the required ingredients

While Defendants' proposed construction improperly imports limitations from the specification into the claim, the LAH/Ethypharm constructions are taken directly from the claim language itself, which is the primary starting point of any claim construction analysis. *See Innova/Pure Water, Inc.*, 381 F.3d at 1116 (noting that "a claim construction analysis must begin and remain centered on the claim language itself"). Claims 1 and 19 of the '574 patent set forth precisely what the inventors intended a "granule" to be—namely, that "each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant."[2] Lesciotto Ex. A at 10:29-32;

[2] Claim 19 contains slightly different wording, referring to a "solubilization agent" in place of "solubilization adjuvant" in claim 1. The parties agree that "binding cellulose derivative as a solubilization adjuvant" and "binding cellulose derivative as a solubilization agent" should have the same meaning, although they disagree as to what that meaning should be. For sake of brevity, this brief will refer only to claim 1 and the term "solubilization adjuvant," although it should be understood that the arguments presented in favor of the LAH/Ethypharm proposed construction for "solubilization adjuvant" are equally applicable to claim 19 and the term "solubilization agent."

11:31-34. Thus, as the claim language is clear on its face, this Court need only review the remaining intrinsic evidence to determine whether some deviation from this language is warranted. *See Interactive Gift Express, Inc.*, 256 F.3d at 1331.

This plain reading of claims 1 and 19 of the '574 patent is clearly supported by the '574 patent's prosecution history. Specifically, in distinguishing a prior art formulation during prosecution, the patentees stated that "[t]he [prior art] compositions are fabricated by a wet granulation method, which produces a composition lacking *the granular structure of the instant claims, which require a neutral core coated with fenofibrate, surfactant and binder*." Lesciotto Ex. C at 10 (emphasis added). This understanding was confirmed by the Examiner, who stated that the "[i]nstant claims are drawn to a pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising micronized fenofibrate, surfactant, and a cellulose binder." Lesciotto Ex. I at p. 3 of Examiner's Amendment. The prosecution history provides no support for any suggested deviation from the plain meaning of the clearly expressed language of claims 1 and 19.

As previously noted, the LAH/Ethypharm proposed construction for "granule" follows the precise wording of the claims. The plural of "granule" does not need any separate construction, as proposed by Defendants. Rather, "granules" simply means more than one granule. This construction is firmly encompassed by the LAH/Ethypharm proposal, which is simply a plural version of the proposed construction for "granule." Adopting this construction of "granules" maintains consistency with the plain language of the claims themselves, and avoids unnecessarily introducing further terms, which would then also need to be construed by the Court. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1328 (declining to give "'plurality . . . of projections' any definition other than its ordinary definition of 'two or

more'"). *See also Phillips*, 415 F.3d at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.") (quoting *Renishaw PLC*, 158 F.3d at 1250); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed. Cir. 1997) ("[T]he language of the claim frames and ultimately resolves all issues of claim interpretation.").

Finally, with the meaning of "granule" already established, there is no need for the Court to spend additional time construing the simple phrase "each granule." Adding excess verbiage to an easily understandable phrase is in opposition to the very purpose of these claim construction proceedings. *See Phillips*, 415 F.3d at 1314 (noting that when the ordinary meaning of claim language is apparent to lay judges, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words").

Defendants go beyond simply deviating from the clear language of the claims and propose a construction that directly conflicts with well-established precedent prohibiting the importation of limitations from the specification. Specifically, Defendants attempt to limit "granule" to a "neutral microgranule on which is *sprayed a suspension* of micronized fenofibrate, a surfactant and a binding cellulose derivative as a solubilization adjuvant/agent." Neither of the independent claims of the '574 patent require that the composition of micronized fenofibrate, surfactant, and binding cellulose derivative as a solubilization adjuvant/agent be a "suspension" which must be "sprayed" onto the neutral microgranule.

Defendants appear to be importing a single sentence from the specification into their proposed construction. This lone sentence states: "The assembly of neutral microgranules is carried out by spraying an aqueous suspension containing the surfactant, the solubilized binding cellulose derivative, and the micronized fenofibrate in suspension." Lesciotto Ex. A at 3:12-15.

However, the context of this isolated statement illuminates its true meaning. Notably, this statement occurs after an introductory paragraph referring to one of the *methods* of preparation taught by the patent, and not to the *pharmaceutical compositions* themselves. *Id.* at 3:1-5.

Further, the only claim which requires a specific method of application of the fenofibrate composition onto the neutral microgranule is claim 11, which recites a method for preparing the pharmaceutical compositions of claim 1 that involves spraying onto neutral microgranules an aqueous solution comprising micronized fenofibrate, surfactant, and solubilized binding cellulose derivative. *Id.* at 10:66-11:3. Defendants' proposed construction attempts to import process limitations from method claim 11 into claims relating to the pharmaceutical compositions, thus violating the long-standing doctrine of claim differentiation. *See, e.g.*, *Phillips*, 415 F.3d at 1314-15 (noting that "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim").

Most importantly, however, is the fact that Defendants' proposed construction is contrary to the prosecution history of the '574 patent. In a Supplemental Response, submitted just prior to the Notice of Allowance, the patentees stated the following:

> The Examiner suggested an examiner's amendment to claims 1 and 21 [renumbered as independent claims 1 and 19 in the '574 patent] to delete the term "disposed" at line 2 of both of those claims. The Examiner stated that such amendment would clarify that the claim does not contemplate any particular form of deposition onto the neutral microgranule, but rather that the described composition is merely present on the neutral microgranule. ***Applicants confirmed that their use of the term "disposed" does not contemplate any particular form of deposition on the neutral microgranule***, and agreed to the proposed Examiner's amendment. . .

Lesciotto Ex. J at pp. 8-9 (emphasis added). The LAH/Ethypharm proposed construction most accurately reflects the plain language of the claim and the express understanding of the Examiner

and patentees, as noted in the prosecution history, while also providing for the required differentiation between independent and dependent claims.

Finally, Defendants' construction for "granules" in the '574 patent finds no tenable support from the claims, specification, or prosecution history. The only reference to "many discrete" granules occurs in the prosecution history of the '331 patent. However, statements made while prosecuting the '331 patent, particularly those made after the '574 patent had already issued, are not properly attributable to a parent patent such as the '574 patent. *See* Section III.A., *supra*. Further, their proposed construction would only beg the inevitable question of what is intended by the words "many" and "discrete." The term "granules" is expressly defined by the plain language of the claims.

2. "Granules" in the '331 Patent

Disputed Term	LAH's/Ethypharm's Construction	Defendants' Construction
"granules"	Neutral cores on which there is micronized fenofibrate	many discrete granules

LAH and Ethypharm see no need for the Court to look beyond the plain language of the claims to construe "granules" with respect to the '331 patent. Claim 1 of the '331 patent is emphatically clear as to what comprises "granules"—some number of neutral cores with an active layer which includes the active pharmaceutical ingredient, micronized fenofibrate. When the claim language is this clear, a Court's only concern is whether the remaining intrinsic evidence demands a deviation from the claim language. *See Interactive Gift Express, Inc.*, 256 F.3d at 1331.

The prosecution history allows for no such deviation. In describing the invention of the '331 patent to the PTO during prosecution, the patentees stated that the claimed method involves administering a pharmaceutical composition comprising granules "of neutral cores coated with an active layer of micronized fenofibrate." Lesciotto Ex. K at p. 6. Providing an illustration of

the invention, the patentees also noted that "the granules can be envisioned as a sphere such as an orange wherein the fruit is the neural core and the rind is the active layer." *Id.* The micronized fenofibrate is the component which makes the active layer "active." Only the LAH/Ethypharm proposed construction comports with the claim language and intrinsic evidence.

Since Defendants continue to fail to acknowledge that the '574 and '331 patents are distinct, and each has an independent body of intrinsic evidence, their proposed construction for "granules" in the '331 patent suffers from the same deficiencies outlined above with respect to their proposal for the '574 patent. Defendants have offered an ambiguous proposal which will only require further claim construction to define what is meant by "many" and "discrete." Construing a plural term requires no more than adherence to the English language—"granules" simply means more than one granule, as properly informed by the plain language of the claims. *See Dayco Prods., Inc.*, 258 F.3d at 1328 (declining to give "'plurality . . . of projections' any definition other than its ordinary definition of 'two or more'").

D. Terms Relating to the Internal Granular Structure

1. "Neutral microgranule" in the '574 Patent

Plaintiffs' Construction	Defendants' Construction
A therapeutically neutral substrate or region of a substrate.	Sugar or sugar mixed with starch particle having a size of between 200 and 1,000 microns and containing no fenofibrate.

Consistent with their other proposed constructions, Defendants again attempt to import limitations from the specifications and, in further conflict with established claim construction precedent, attempt to import limitations not found anywhere within the '574 patent or its prosecution history. Such a proposal is an invitation to legal error. While courts are permitted, and indeed encouraged, to look to the specification for the proper context for disputed claim terms, "care must be taken to avoid reading 'limitations appearing in the specification . . . into

[the] claims.'" *Interactive Gift Express, Inc.*, 256 F.3d at 1331 (quoting *Intervet Am., Inc. v. Kee-Vet Labs., Inc.* 887 F.2d 1050, 1053 (Fed. Cir. 1989) (omission and correction in original)). Indeed, the claims are not a "nose of wax" which Defendants are free to mold to their particular liking. *See White*, 119 U.S. at 51-52.

Defendants have no support for their proposed construction in the claims, the specification, or the prosecution history. Nothing in the totality of the intrinsic evidence indicates any intention or need to so narrowly limit the "neutral microgranule" to a particular substrate and particular size range, as Defendants propose.

First, Defendants' proposal that a "neutral microgranule" be "sugar or sugar mixed with starch particle" appears to have been either plucked from thin air or imported from the prosecution history of the '331 patent, neither of which is permissible. Nothing in the '574 patent or prosecution history evidences a limitation on the type of substrate which may function as a "neutral microgranule" in the '574 patent to be sugar or sugar mixed with starch. *See Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1290 (Fed. Cir. 2000) ("This court has repeatedly and clearly held that it will not read unstated limitations into claim language."); s*ee also Dayco Prods., Inc.*, 258 F.3d at 1324 ("If an argument offered in support of a particular claim construction is so convoluted and artificial that it would not be apparent to a skilled artisan reading the patent and the prosecution history, the argument is simply unhelpful to the performance of our task."); *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330 (Fed. Cir. 2008) (criticizing a party's proposed construction which required the disputed claim term to mean "something beyond the breadth of anything in the claims or the specification"). While claim 1 of the '331 patent describes a "neutral core [which] comprises a sugar or a sugar mixed with starch," there is no authority to support the upstream application of statements made in the

'331 child patent to the claim terms of the '574 parent patent, especially as the terms in this instance are materially different—*i.e.*, "neutral microgranule" in the '574 patent versus "neutral core" in the '331 patent. *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1382 (Fed. Cir. 2003) (reversing a construction of claims of two related patents as synonymous when the claim language was significantly different). *See Winn Inc.*, 272 F. Supp. 2d at 977 n.5 (noting the lack of authority for and rejecting the use of "a subsequent patent to determine the meaning of claim terms used in a prior patent"); *Epic Metals Corp.*, 19 F. Supp. 2d at 1303 (concluding that a continuation-in-part patent's specification and prosecution history was extrinsic evidence with respect to construing claims of the parent patent and rejecting such extrinsic evidence as a "disserv[ice to] the public's right to rely on the [parent] patent's language").

Second, Defendants' proposed construction of "neutral microgranule" improperly imports a particle size limitation from a portion of the specification referring to a "first variant" of a *method* for preparing the granules. Lesciotto Ex. A at 3:1-8. The portion of the specification referring to *methods* for preparing certain compositions is distinct from the portion describing the *pharmaceutical compositions* themselves. The only claims at issue are those directed to the inventive pharmaceutical compositions. Thus, it is improper for Defendants to propose an embellished construction for "neutral microgranule" that incorporates limitations from an isolated embodiment noted in the specification as related only to a method of preparation. *See Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008) ("Courts must generally take care to avoid reading process limitations into an apparatus claim because the process by which a product is made is irrelevant to the question of whether that product infringes a pure apparatus claim."); *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (noting that the "method of manufacture, even when

cited as advantageous, does not of itself convert product claims into claims limited to a particular process").

In contrast, the LAH/Ethypharm proposed construction fully comports with the intrinsic evidence, without importing limitations from the specification which are unrelated to the claimed pharmaceutical compositions. It is clear that the patentees did not intend to limit the neutral microgranule to any particular substrate, as neither the specification nor the prosecution history offers support for such limitations. Likewise, while the prefix "micro" in "microgranule" obviously requires the granule to be small in size, there is nothing in the claims, specification, or prosecution history that justifies imposing a particular size range for the microgranule. *See Innova/Pure Water, Inc.*, 381 F.3d at 1117 (noting that "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect"). Whether a substrate is of a size that constitutes a "*micro*granule" is a question of fact, rather than a question that should be answered by importing limitations from the specification into the construction of the term.

The only limitations clearly intended by the claims and specification are that the microgranule (1) be therapeutically neutral, and (2) have a surface capable of supporting a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant. Lesciotto Ex. A at 10:28-38; 11:30-35. The LAH/Ethypharm construction accurately reflects this intention by requiring that the "neutral microgranule" be a therapeutically neutral substrate or region of a substrate, without improperly importing limitations from the specification.

2. "Neutral core" in the '331 Patent

Plaintiffs' Construction	Defendants' Construction
A pharmaceutically neutral substrate to which active layer can be applied.	Sugar or sugar mixed with starch particle having a size of between 200 and 1,000 microns and containing no fenofibrate.

Defendants again improperly import limitations from the specification The size limitation of "between 200 and 1,000 microns" proposed by Defendants is only found in the portion of the specification referring to methods for *preparing granules*, which refers to neutral cores as having a particle size range. Lesciotto Ex. B at 5:64-6:2. The claims at issue are directed to methods of *reducing food effect*. Defendants' construction improperly relies upon a reference to particle size that appears in a portion of the specification relating to methods of preparing granules. Reliance upon a portion of the specification unrelated to the claim term is improper. *See Intamin, Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1335 (Fed. Cir. 2007) (noting that "a narrow disclosure in the specification does not necessarily limit broader claim language"). Further, the "sugar or starch mixed with sugar" language is already present in claim 1 of the '331 patent, which states that the neutral core "comprises a sugar or a sugar mixed with starch." Lesciotto Ex. B at 16:60-61.

The only limitations required by the claims and specification are that the neutral core (1) be pharmaceutically neutral and (2) have a surface to which the active layer can be applied. *Id.* at 16:57-58. Only the LAH/Ethypharm proposed construction correctly captures this objective without improperly importing limitations from the specification or prosecution history.

E. Terms Related to the Binding Cellulose Derivative

1. "Binding cellulose derivative as a solubilization adjuvant/agent"[3] in the '574 patent

Plaintiffs' Construction	Defendants' Construction
A cellulose-based polymer in said pharmaceutical composition that binds the micronized fenofibrate to the neutral microgranule and increases the micronized fenofibrate's solubility and/or rate of solubilization	any and all water-soluble cellulose-based polymer, such as HPMC, in the pharmaceutical composition that is capable of binding micronized fenofibrate to the neutral microgranule and increasing the micronized fenofibrate's solubility or rate of solubilization

Claim 1 requires "a *binding* cellulose derivative *as a solubilization adjuvant*." Lesciotto Ex. A at 10:31-32 (emphasis added). This language clearly requires that the cellulose derivative actually performs two distinct functions: (1) binding the active component, the micronized fenofibrate, to the neutral microgranule and (2) acting as a solubilization adjuvant. The specification supports this dual-function interpretation of the cellulose derivative, referring to the unexpected advantages found when incorporating a "cellulose derivative, *used* as a binder *and* solubilization adjuvant" into a pharmaceutical composition containing micronized fenofibrate and a surfactant. *Id.* at 2:4-10 (emphasis added).

Defendants' use of "any and all" as a modifier to capture all cellulose derivatives that are merely *capable* of binding the micronized fenofibrate and increasing its solubility and/or rate of solubilization ignores the more limiting claim language. The claim language is clear that the only cellulose derivative being described as part of the pharmaceutical composition is a cellulose

[3] As noted earlier, independent claims 1 and 19 of the '574 patent refer, respectively, to a "binding cellulose derivative as a solubilization adjuvant" and "binding cellulose derivative as a solubilization agent." The parties agree that "binding cellulose derivative as a solubilization adjuvant" and "binding cellulose derivative as a solubilization agent" should have the same meaning, although they disagree as to what that meaning should be. For brevity, this brief will continue to refer only to claim 1 and the term "solubilization adjuvant," although it should be understood that the arguments presented in favor of the LAH/Ethypharm proposed construction for "solubilization adjuvant" are equally applicable to claim 19 and the term "solubilization agent."

derivative that functions both to bind the micronized fenofibrate to the neutral microgranule and also to increase the micronized fenofibrate's solubility and/or the rate of solubilization. *Id.* at 10:33-34. Indeed, the specific weight percentages of binding cellulose derivative are premised only on that portion of the cellulose derivative included in the composition which embodies this dual-function—not any and all possible cellulose derivatives that may be added to a pharmaceutical composition for any number of other reasons or purposes. *Id.*

As the specification of the '574 patent makes clear, the binding cellulose derivative is not merely that which is "capable" of binding the micronized fenofibrate to the neutral microgranule or "capable" of increasing the micronized fenofibrate's solubility or rate of solubilization, as Defendants propose. Rather, the binding cellulose derivative must function to bind the active component, the micronized fenofibrate, to the neutral microgranule. For example, the specification states that "it has been discovered that the incorporation of a cellulose derivative *as a binder and solubilization adjuvant*, into a composition containing micronized fenofibrate and a surfactant makes it possible to obtain a bioavailability which is greater than for a composition containing a comicronizate of fenofibrate and of a surfactant." *Id.* at 2:4-10. The claims themselves make clear that "each granule comprises a neutral microgranule *on which* is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant." *Id.* at 10:28-32 (emphasis added).

Similarly, the specification and prosecution history clearly require that the binding cellulose derivative must act to increase the micronized fenofibrate's solubility and/or rate of solubilization. The patentees stated during prosecution of the '574 patent:

> While preparing Applicants' formulation, [the cellulose derivative] polymer is intimately mixed with the fenofibrate microparticles, allowed by the solubilization of the polymer in the suspension which contains the microparticles of fenofibrate and the surfactant.

> It is performed by the recrystallization of the molecules of the polymer onto the surface of the particle of the active principle during drying, forming a layer of hydrophilic molecules onto the surface of the insoluble particles of the active principle, thereby *making them soluble (or more soluble), and increasing the bioavailability of fenofibrate*.

Lesciotto Ex. L at pp. 13-14 (emphasis added). Thus, the clear import of the patent and the prosecution history is that the cellulose derivative molecules (1) are in contact with the micronized fenofibrate particles and further bind the fenofibrate particles to the neutral microgranules, and (2) increase the micronized fenofibrate's solubility and/or rate of solubilization. The LAH/Ethypharm proposal is the only offered construction which appropriately incorporates this express understanding that is firmly rooted in the patent's claims and specification.

2. "Hydroxypropylmethylcellulose" in the '331 patent

Plaintiffs' Construction	Defendants' Construction
A cellulose hydroxypropylmethyl ether that acts to bind the micronized fenofibrate to the neutral core and increases the micronized fenofibrate's solubility and/or rate of solubilization	the total of any and all grades of HPMC in the pharmaceutical composition

Hydroxypropylmethylcellulose is also known in the art by the term HPMC, and for the sake of brevity, that term will be used. HPMC, chemically, is a cellulose hydroxypropylmethyl ether. Accordingly, LAH/Ethypharm have used the term "a cellulose hydroxypropylmethyl ether" in their claim construction. LAH/Ethypharm also incorporate the functionality of the HPMC into the definition for reasons similar to those expressed with respect to the "binding cellulose derivative" in the '574 patent. Throughout the specification of the '331 patent, the patentees identified a "binding cellulose derivative" as part of the claimed invention, and this "binding cellulose derivative" was described as having a similar dual-function to the binding

cellulose derivative of the '574 patent. *See, e.g.*, Lesciotto Ex. B at 2:28-30; 2:49-54. During prosecution, the claim term "binding cellulose derivative" was replaced with "hydroxypropylmethylcellulose" in what became claim 1 of the '331 patent. Lesciotto Ex. M at p. 2 of Supplementary Examiner's Amendment; Lesciotto Ex. N at p. 2 of Examiner's Amendment. Thus, LAH/Ethypharm have proposed a construction for the term "hydroxypropylmethylcellulose" that is analogous to the proposed construction for the term "binding cellulose derivative" in the '574 patent. *See* Section III.E.1., *supra*.

Defendants' proposed construction attempts to encompass "any and all" grades of HPMC occurring anywhere, whether part of the claimed pharmaceutical composition or not and without regard to whether the HPMC is actually functioning to bind fenofibrate to the neutral core. First, it is abundantly apparent that the "hydroxypropylmethylcellulose" referred to in claim 1 of the '331 patent is only the HPMC that is contained in the active layer. Lesciotto Ex. B at 16:62-63. Second, both the specification and the prosecution history are clear that the "hydroxypropylmethylcellulose" must have the described dual-functions. *See, e.g., id.* at 2:28-30 ("it has been discovered that the incorporation of a cellulose derivative, *used as a binder and solubilization adjuvant*. . ."); 2:49-54 ("molecules of both cellulose derivative and surfactant are adsorbed directly onto the fenofibrate microparticles . . . which are *responsible for its better solubilization*"); Lesciotto Ex. O at p. 11 ("As such, applicants restrict the claimed quantities of binding cellulose derivative by excluding from [the weight] calculation other agents and excipients . . ."). Clearly, the "hydroxypropylmethylcellulose" of the '331 patent is limited to only the HPMC included in the active layer which acts (1) to bind the micronized fenofibrate to the neutral core and (2) to increase the micronized fenofibrate's solubility and/or rate of

solubilization. Only the LAH/Ethypharm proposed construction comports with this unambiguous disclosure and intention.

F. "Micronized fenofibrate" in the '574 patent and the '331 patent

Plaintiffs' Construction	Defendants' Construction
Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule

The LAH/Ethypharm construction defines "micronized fenofibrate" based on art-recognized properties. Fenofibrate that was originally approved for use by the United States Food and Drug Administration ("FDA") had dissolution problems and therefore lower than desired absorption when administered to a patient. It was later recognized that fenofibrate with a smaller particle size would be beneficial by providing improved solubility and/or rate of solubilization. *See, e.g.*, Lesciotto Ex. A at 1:23-33.

Both the '574 patent and the '331 patent clearly state that "micronized fenofibrate" serves to increase the rate of solubilization: "Various approaches have been explored in order to increase the rate of solubilization of fenofibrate: micronization of the active principle. . ." Lesciotto Ex. A at 1:27-29; Lesciotto Ex. B at 1:49-51. Thus micronized fenofibrate has an enhanced rate of solubilization as compared to non-micronized fenofibrate. This is accurately captured in the LAH/Ethypharm construction.

Defining micronized fenofibrate by its improved solubility and dissolution rate as compared to non-micronized fenofibrate is well-established. For example, in Munoz, A., et. al., "Micronised fenofibrate," *Atherosclerosis*, Vol. 110 (Suppl.), pp. S45-S48 (1994) (Lesciotto Ex. P), at page S436, a graphic representation of the improvement in both solubility and dissolution

rate is shown, when micronized fenofibrate is compared to non-micronized fenofibrate (shown as "fenofibrate powder"). The results are discussed at page S47: "[A]fter 40 min, about 95% of micronised fenofibrate is solubilised, whereas only 50% of non-micronised fenofibrate is dissolved during the same time."

Further, the LAH/Ethypharm construction reflects the well-known idea that "micronized fenofibrate" particles are of a smaller size than non-micronized fenofibrate without having to import inappropriate limitations from the specification. Defendants attempt to limit the claims by requiring an unreasonably narrow particle size that is unsupported by the specification. Their proposed construction imparts a strict limit that all of the fenofibrate particles be "of a size less than 15 microns." However, the specifications of both the '574 and '331 patents only state that "[t]he *mean* size of the fenofibrate particles is less than 15 µm." Lesciotto Ex. A at 2:58-59; Lesciotto Ex. B at 4:13-15. Further, both patents describe prior art formulations having micronized fenofibrate particles as large as 50 µm in size. Lesciotto Ex. A at 1:32-35; Lesciotto Ex. B at 1:53-56. There is no basis in the specification to support a size limitation as narrow as Defendants propose.

Additionally, Defendants' proposed construction goes beyond interpreting what is meant by the specific term "micronized fenofibrate," and instead attempts to introduce unrelated limitations in contravention of Federal Circuit law. *See Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("[I]nterpreting what is *meant* by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.") (citations omitted; emphasis in original). Defendants attempt to limit the claims by requiring that the micronized fenofibrate be free of other possible ingredients when micronized, or be present in an "aqueous suspension." Simply put, Defendants' proposal includes limitations

not even remotely associated with the term "micronized fenofibrate." *See Johnson Worldwide Assocs., Inc.*, 175 F.3d at 990 (noting that "there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction"); *Northern Telecom Ltd.*, 215 F.3d at 1290 ("This court has repeatedly and clearly held that it will not read unstated limitations into claim language."). *See also NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005) (requiring a textual hook in the claim language before using a statement from the specification to confine the claim).

G. "Surfactant" in the '574 patent and the '331 patent

Plaintiffs' Construction	Defendants' Construction
A substance which lowers the surface tension of water.	An amphiphilic, surface-tension lowering substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone[4]

For this particular disputed claim term, the use of extrinsic evidence is warranted, as neither the patent nor the prosecution history provides a definition, express or implicit, for "surfactant." The Federal Circuit has approved of the use of extrinsic evidence in such circumstances and noted the particular usefulness of technical treatises and dictionaries. "Judges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Vitronics Corp.*, 90 F.3d at 1584 n.6.

[4] Defendants' construction for "surfactant" differs from that presented in the Joint Claim Construction and Prehearing Statement filed on June 15, 2011 (Dkt. 3). LAH and Ethypharm were notified on the afternoon of June 21st, the day opening briefs were to be filed, that Defendants "had reached a consensus on their construction of 'surfactant.'" Lesciotto Ex. V. In presenting this eleventh hour change, Defendants asserted that the new construction did not "add any language that was not in the individual constructions previously presented." *Id.*

However, the extrinsic evidence demonstrates that Defendants' construction is far too narrow. In contrast, the LAH/Ethypharm proposed definition is in accordance with the definitions provided by various technical treatises and dictionaries available as of the effective filing date of the patents.[5] *See Phillips*, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application"). For example, several relevant technical dictionaries provide the following definitions for surfactant or surface-active agent:

- "A compound that reduces the surface tension of its solvent," Chambers Dictionary of Science and Technology at p. 1133 (1999) (Lesciotto Ex. Q);
- "Surface-active agent. (surfactant). Any compound that reduces surface tension when dissolved in water or water solutions, or that reduces interfacial tension between two liquids, or between a liquid and a solid," Hawley's Condensed Chemical Dictionary at 1066 (13th ed. 1997) (Lesciotto Ex. R); and
- "Surface-active agent . . . A soluble compound that reduces the surface tension of liquids, or reduces interfacial tension between two liquids or a liquid and a solid. Also known as surfactant," McGraw-Hill Dictionary of Scientific and Technical Terms at 1960 (5th ed. 1994) (Lesciotto Ex. S).

Each of these definitions supports the LAH/Ethypharm construction.

Defendants' proposed construction seeks to inappropriately limit "surfactant" in ways that are unsupported by the specification, the prosecution history, or the extrinsic evidence. For example, both constructions seek to exclude "anti-foaming agents such as simethicone." However, there is no support for such an exclusion, as nothing in the specification states that an anti-foaming agent could not also be a surfactant if it acts to lower the surface tension of water. *See Epistar Corp. v. ITC*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) ("[Defendants] must establish

[5] The '574 patent claims priority to French Patent Application No. 99 08923, filed July 9, 1999. The '331 patent claims priority to the '574 patent as well as the parent French Patent Application.

the inventors demonstrate[d] an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.") (internal quotations omitted). The patentees offered no such "clear disavowal" as to what compounds could be considered a "surfactant," so long as the compound fit the well-accepted meaning of "surfactant," as outlined above.

As is clear from the extrinsic evidence described above, only the LAH/Ethypharm proposed construction comports with the understanding that a person of ordinary skill in the art would have had as to the definition of "surfactant" in 1999 in accordance with Federal Circuit precedent. *See Kegel Co. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1427 (Fed. Cir. 1997) ("Without an express intent to impart a novel meaning to a claim term, the term takes on its ordinary meaning.").

H. "Active layer" in the '331 patent

Plaintiffs' Construction	Defendants' Construction
A mixture of micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose	layer comprised of micronized fenofibrate, surfactant, and binding cellulose derivative sprayed on the outside of the neutral core

LAH/Ethypharm note at the outset that Defendants' proposed construction of the term "active layer" does not contradict the LAH/Ethypharm construction of "a mixture of micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose," inasmuch as a portion of Defendants' proposed construction recites "micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose." Defendants could not contradict LAH/Ethypharm's proposed construction in this regard, as claim 1 of the '331 patent clearly defines the "active layer" as

comprising a mixture of "the micronized fenofibrate, the surfactant, and [hydroxypropylmethylcellulose]."[6] Lesciotto Ex. B at 16:61-63.

Accordingly, then, the only recourse left to Defendants to mold "active layer" to their liking is to improperly introduce unwarranted limitations from the specification into the claims of the '331 patent. Namely, Defendants' construction improperly imports the specification's mention of "spraying" as one possible method for preparing the granules into the claims as a required limitation. Specifically, references in the specification to "spraying" a mixture of micronized fenofibrate, surfactant, and hydroxypropylmethylcellulose occur with respect only to *possible* methods for preparing granules. *See, e.g., id.* at 3:15-20 ("These granules *may* in particular be prepared by assembly on neutral cores, by spraying . . ."). This is not equivalent to a requirement that the "active layer" be "sprayed on the outside of the neutral core." *See Dayco Prods., Inc.*, 258 F.3d at 1327 (noting that "adding limitations to claims not required by the claim terms themselves, or *unambiguously required* by the specification or the prosecution history, is impermissible") (emphasis added). The LAH/Ethypharm construction avoids this legal error by staying true to the claim language and avoids introducing unwarranted process limitations into the claims.

I. "Sugar" in the '331 patent

Plaintiffs' Construction	Defendants' Construction
Lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide	lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide; not a starch or other polysaccharide

[6] It is noted that a publication error appears in claim 1 of the '331 patent. A Supplementary Examiner's Amendment, dated November 2, 2009, changed all references of "binding cellulose derivative" to "hydroxypropylmethylcellulose" (*see* Lesciotto Ex. M at p. 2; *see also* Lesciotto Ex. N at p. 2), and the patentees agreed to the entry of such an amendment.

All of the parties agree that "sugar," as used in the '331 patent, includes lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharides or other lower oligosaccharides. This is consistent with the intrinsic evidence. *See, e.g.*, Lesciotto Ex. B at 3:28-29 ("wherein said neutral core may include lactose, mannitol, a mixture of sucrose and starch or any other acceptable sugar"); Lesciotto Ex. T at p. 5 ("the neutral core comprises any pharmaceutically acceptable sugar (including, but not limited to, lactose, mannitol, and/or sucrose) and may further comprise starch").

However, Defendants refuse to be satisfied with a construction that accurately reflects both the specification and the prosecution history. Instead, Defendants seek to define not only what a "sugar" is but also what a "sugar" is not. LAH and Ethypharm see no need for such exclusionary language. When a term can be clearly and adequately defined through affirmative language, there is no need to attach exclusionary language. In the process of so doing, Defendants attempt to import yet another unwarranted limitation into the claims of the '331 patent. Accordingly, Defendants' proposal should rejected.

J. The "Wherein" clauses in the '574 patent and '331 patent

1. The '574 patent

Disputed Terms of the '574 Patent	LAH/Ethypharm Construction	Defendants' Construction
wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 must be greater than or equal to 60[7]	weight of all of the micronized fenofibrate in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 must be greater than or equal to 60

[7] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the terms "micronized fenofibrate" and "said pharmaceutical composition."

wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition	weight of said binding cellulose derivative as a solubilization adjuvant/agent in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 is between 2 to 15[8]	weight of all of the binding cellulose derivative in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 2 to 15
wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of binding cellulose derivative as a solubilization adjuvant/agent is between 5 and 15[9]	weight of all of the micronized fenofibrate divided by the weight of all of the binding cellulose derivative is between 5 and 15

The LAH/Ethypharm proposed constructions are firmly rooted in the plain language of the claims, the '574 patent's specification, and the prosecution history. Defendants, however, continue to improperly attempt to cast a broad net around "all" components in the final dosage form in direct contradiction to the plain language of the claims.

For example, and as discussed in Section III.B.1., *supra*, Defendants have proposed that "pharmaceutical composition" be construed as "*all* of the *active and inactive* ingredients in the final dosage form." Under Defendants' proposed construction, it would follow that the "weight of said pharmaceutical composition" would include every component in the "final dosage form" regardless of whether that component is identified by the plain language of the claims as being part of "said pharmaceutical composition." However, the claims of the '574 patent clearly limit "said pharmaceutical composition" to only the granules which comprise a neutral microgranule

[8] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "binding cellulose derivative as a solubilization adjuvant/agent" and "said pharmaceutical composition."

[9] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate" and "binding cellulose derivative as a solubilization adjuvant/agent."

on which is a composition comprising micronized fenofibrate, a surfactant, and a binding cellulose derivative. Lesciotto Ex. A at 10:28-38; 11:30-35. *See also* Section III.B.1, *supra*. No other ingredients are recited as being included in the claimed composition.

Further, Defendants cannot support their position by reference to the '574 patent's prosecution history. As noted previously in Section III.B.1., *supra*, in describing the second declaration of George Bobotas, Ph.D., the patentees noted that Dr. Bobotas calculated the weight percentages of micronized fenofibrate and binding cellulose derivative in Antara®, a commercial embodiment of the '574 patent. Dr. Bobotas' calculations in this regard were based *only on the weight of the granules*, each of which comprises a neutral microgranule on which is a composition. Specifically, the claims of the '574 patent recite greater than or equal to 60% by weight fenofibrate and between 2 and 15% by weight binding cellulose derivative, relative to the weight of "said pharmaceutical composition." Lesciotto Ex. A at 10:28-38; 11:30-35. Dr. Bobotas calculated the weight percentages of micronized fenofibrate and binding cellulose derivative in Antara® as follows: "The 130 mg ANTARA® formulation of the invention is 64% fenofibrate by weight *relative to the weight of the granules*, and 12% by weight binding cellulose derivative, *relative to the weight of the granules*. Thus, the 130 mg ANTARA® formulation is within the instant claims." Lesciotto Ex. D at 10 (internal citation omitted) (emphasis added). *See also* Lesciotto Ex. E at p. 2, ¶ 4. Clearly, then, the term "said pharmaceutical composition" as used in the claims of the '574 patent, refers only to the coated granules—not "all of the active and inactive ingredients in the final dosage form," as Defendants propose.

Defendants' proposal for "binding cellulose derivative as a solubilization adjuvant/agent" leads to equally inconsistent results when applied to the claim terms listed above. Instead, only the portion of the cellulose derivative that functions as both a binder and a solubilization

adjuvant should be included in the weight of the "binding cellulose derivative as a solubilization adjuvant/agent." *See, supra,* Section III.E.1. (discussing the constructions for "binding cellulose derivative as a solubilization adjuvant/agent"). Only the LAH/Ethypharm proposed construction is consistent with the intrinsic evidence.

2. The '331 Patent

Disputed Terms of the '331 Patent	LAH/Ethypharm Construction	Defendants' Construction
wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1	weight of said micronized fenofibrate in the composition divided by the weight of said hydroxypropylmethylcellulose in the composition is between 5 and 15[10]	weight of all of the micronized fenofibrate divided by the weight of all of the hydroxypropylmethylcellulose is between 5 and 15
said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition	weight of said hydroxypropylmethylcellulose in the composition divided by the weight of the composition times 100 is between 5 to 12[11]	weight of all of the hydroxypropylmethylcellulose in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 5 and 12

Defendants' proposed constructions are, if nothing else, consistent, as they again cast a broad net around "all" components in the final dosage form in direct contradiction to the plain language of the claims.

As with the '574 patent, Defendants' construction is that the "pharmaceutical composition" and "the composition" terms of the '331 patent be construed as "all of the active and inactive ingredients in the final dosage form." *See, supra*, Section III.B.2. Given Defendants' erroneous proposed construction, it would follow that the "weight of the

[10] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate," "the composition" and "hydroxypropylmethylcellulose."

[11] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "hydroxypropylmethylcellulose" and "the composition."

composition" would include every component in the "final dosage form," regardless of whether that component is identified by the plain language of the claims as being part of "the composition." However, claim 1 of the '331 patent provides clear limits on what constitutes "the composition"—namely, granules comprising a neutral core and an active layer. Lesciotto Ex. B at 16:55-58. Indeed, throughout the prosecution history, the patentees emphasized that the weight percentage of the hydroxypropylmethylcellulose was calculated relative to the "weight of the combination of the neutral core, the fenofibrate, the surfactant, and the [hydroxypropylmethylcellulose]." Lesciotto Ex. O at p. 11 (amending claims to clarify that "the binding cellulose derivative is measured relative to the combination of only the neutral core, and the fenofibrate, the surfactant, and the binding cellulose derivative of the active layer. As such, applicants restrict the claimed quantities of binding cellulose derivative by excluding from that calculation other agents and excipients. . ."); Lesciotto Ex. U at p. 6 ("Applicants have likewise confined the calculation of the percent of binding cellulose derivative to a percentage by weight of the neutral core, fenofibrate, surfactant, and binding cellulose derivative.").

Similarly, Defendants' proposal for "hydroxypropylmethylcellulose" leads to equally inconsistent results. As clearly envisioned by the patentees, only the portion of the hydroxypropylmethylcellulose which functions as both a binder and a solubilization adjuvant should be included as the weight of said hydroxypropylmethylcellulose for purposes of the weight ratios and percentages outlined in the claims. *See, supra,* Section III.E.2. (discussing the constructions for "hydroxypropylmethylcellulose"). Only the LAH/Ethypharm proposed construction is consistent with the intrinsic evidence.

A simple illustration demonstrates the error in Defendants' proposals for the "pharmaceutical composition" claim terms present in both the '574 and '331 patents. The claims

of the ’574 and ’331 patents clearly envision what both “said pharmaceutical composition” of the ’574 patent and “the composition” of the ’331 patent are—namely, that the respectively-described compositions are in the form of granules, wherein the granules carry the active ingredient. If these granules were then bound to a rock, under Defendants’ construction, the weight of this rock, as an inactive ingredient, would be included for purposes of calculating the various weight ratios and percentages. Construing a rock to be part of a pharmaceutical composition, which Defendants’ construction would require, is not well-grounded. Defendants cannot argue in good faith that “all of the active *and inactive* ingredients in the final dosage form” are part of the weight of “said pharmaceutical composition” any more than a rock would contribute to the weight of “said pharmaceutical composition.”

IV. CONCLUSION

For the foregoing reasons, LAH/Ethypharm respectfully request that the Court adopt the LAH/Ethypharm proposed constructions of the disputed claim terms.

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APPENDIX A.
Proposed Claim Constructions

Claim Terms of The '574 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
said pharmaceutical composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form
granules	Neutral microgranules on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	many discrete granules
granule	Neutral microgranule on which	neutral microgranule on

	there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	which is sprayed a suspension of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent
each granule	No additional construction necessary	each and every granule in the pharmaceutical composition contains all the required ingredients
neutral microgranule	A therapeutically neutral substrate or region of a substrate	sugar or sugar mixed with starch particle having a size of between 200 and 1,000 microns and containing no fenofibrate
surfactant	A substance that lowers the surface tension of water	An amphiphilic, surface-tension lowering substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone
binding cellulose derivative as a solubilization adjuvant/agent	A cellulose-based polymer in said pharmaceutical composition that binds the micronized fenofibrate to the neutral microgranule and increases the micronized fenofibrate's solubility and/or rate of solubilization	any and all water-soluble cellulose-based polymer, such as HPMC, in the pharmaceutical composition that is capable of binding micronized fenofibrate to the neutral microgranule and increasing the micronized fenofibrate's solubility or rate of solubilization
micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein said fenofibrate is present in an amount greater	weight of said micronized fenofibrate in said	weight of all of the micronized fenofibrate in the

than or equal to 60% by weight, relative to the weight of said pharmaceutical composition	pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 must be greater than or equal to 60[12]	pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 must be greater than or equal to 60
wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition	weight of said binding cellulose derivative as a solubilization adjuvant/agent in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 is between 2 to 15[13]	weight of all of the binding cellulose derivative in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 2 to 15
wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of binding cellulose derivative as a solubilization adjuvant/agent is between 5 and 15[14]	weight of all of the micronized fenofibrate divided by the weight of all of the binding cellulose derivative is between 5 and 15

[12] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the terms "micronized fenofibrate" and "said pharmaceutical composition."

[13] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "binding cellulose derivative as a solubilization adjuvant/agent" and "said pharmaceutical composition."

[14] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate" and "binding cellulose derivative as a solubilization adjuvant/agent."

Claim Terms of the '331 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
the composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising: (a) a neutral core; and (b) an active layer* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form
granules	Neutral cores on which there is micronized fenofibrate	many discrete granules
surfactant	A substance that lowers the surface tension of water	An amphiphilic, surface-tension lowering substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of

		fenofibrate, and does not include anti-foaming agents such as simethicone
hydroxypropylmethylcellulose	A cellulose hydroxypropylmethyl ether that acts to bind the micronized fenofibrate to the neutral core and increases the micronized fenofibrate's solubility and/or rate of solubilization	the total of any and all grades of HPMC in the pharmaceutical composition
neutral core	A pharmaceutically neutral substrate to which active layer can be applied	same as neutral microgranule
active layer	A mixture of micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose	layer comprised of micronized fenofibrate, surfactant, and binding cellulose derivative sprayed on the outside of the neutral core
sugar	Lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide	lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide; not a starch or other polysaccharide
micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1	weight of said micronized fenofibrate in the composition divided by the weight of said hydroxypropylmethylcellulose in the composition is between 5 and 15[15]	weight of all of the micronized fenofibrate divided by the weight of all of the hydroxypropylmethylcellulose is between 5 and 15

[15] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate," "the composition" and "hydroxypropylmethylcellulose."

said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition	weight of said hydroxypropylmethylcellulose in the composition divided by the weight of the composition times 100 is between 5 to 12[16]	weight of all of the hydroxypropylmethylcellulose in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 5 and 12

Claim Terms Having a Definition To Which the Parties Have Agreed

Claim Term	Agreed Definition
binding cellulose derivative	hydroxypropylmethylcellulose[17]

[16] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "hydroxypropylmethylcellulose" and "the composition."

[17] To the extent the Court determines this term is capable of construction, Defendants do not propose a different construction. Defendants reserve their right to argue that this term lacks antecedent basis and renders the claim indefinite under 35 U.S.C. 112.